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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,383	05/03/2005	Stanley George Bonney	P33144USW	3387

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EXAMINER	
OSTRUP, CLINTON T	
ART UNIT	**PAPER NUMBER**
3771	

NOTIFICATION DATE	DELIVERY MODE
01/02/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/534,383	BONNEY ET AL.	
	Examiner	Art Unit	
	Clinton Ostrup	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *2/3/06*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-33* is/are rejected.

7)☒ Claim(s) *19 & 29* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 May 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05/03/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-33 are pending in this application.

Priority

The examiner acknowledges this application was filed as a United States National Phase Application of International Application Serial No. PCT/EP2003/012436 filed November 5, 2003, which claims priority from Great Britain Application No. 0226022.2, filed November 7, 2002.

Claim Objections

Claim 19 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 19 merely recites an intended use of a drug in the device. This intended use of a composition adds no additional structural limitation to a claim for a device.

Regarding claim 29, the phrase "rack-like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d). It is unclear how much the mechanical member must be "rack-like" to be included or excluded by the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7-11, 13-23, 25-27 and 29-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Casper et al., (5,826,571).

Casper et al., teach a drug delivery device (10), and a method of making a drug delivery device, for delivering to a patient a drug composition from a container (12) which contains the drug composition, the container adapted to be placed in a dispensing mode thereof on application of an actuating condition thereto, wherein the device comprises: a dispensing unit (14) adapted to receive the container (12), the dispensing unit having an actuating mechanism (16) operable to apply the actuating condition to the container and an outlet (outlet of MDI) through which the drug composition is dispensable from the device (10); and a removable casing unit (housing of (10)) for the dispensing unit; and wherein: the dispensing (14) and casing units (housing) have securing features (inside housing adapted to hold MDI (14))for releasably, fixedly securing the units together; and the dispensing unit (14) is operable to apply the actuating condition to the container when fixedly secured to the casing unit (housing of (10)) and when independent from the casing unit, thus meeting the limitations of claims 1 and 22. See: col. 4, lines 7-31 and Figure 2

Casper et al., teach that the device (10) has a movable protective dust cap (18) which enables the device (10) to be positioned between a closed state in which it is able to enclose the dispensing unit (14) with the container received therein, and an open state which enables the actuating mechanism of the dispensing unit to be operated to

apply the actuating condition to the container and for the resultant dispensed drug composition to be discharged from the outlet, thus meeting the limitations of claim 2, 23 and 32-33. The device shown in Figures 1 and 2 are hand held devices, thus meeting the limitations of claim 3. See: col. 4, lines 22-28 and Figures 1 & 2.

Casper et al., show the dispensing unit/MDI (14) as being held in place in the device (10) by the inside of the housing, thus meeting the limitations of claims 4. See: Figure 2.

Casper et al., describe that on actuation, the actuation platform (26) contacts aerosol container (12) and pushes it downward until the aerosol canister valve spring inside the canister compresses, thus teaching the actuation condition as claimed in claims 7, 8, and 30 and the valve and container as claimed in claims 16-17 and 31. See: col. 6, line 34 – col. 7, line 14.

In regard to claims 9-11 & 25, Casper et al., teach that the actuating platform (26) is connected to a counter (30) by a connecting rod (40) which advances the counter (38) by one unit for each complete canister actuation/recovery cycle. See: col. 7, lines 8-15.

In regard to claims 13-14 and 18-20, Casper et al., teach the nozzle of the MDI (14) as forming the nozzle for the device (10) for dispensing and directing the medicament to the patient on application of the actuating condition to the container. See: Figure 3.

Casper et al., teach that the MDI (14) ca be removed and replaced, thus teaching the interchangeable dispensing units as claimed in claim 21. See: col. 5, lines 25-33.

Thus, Casper et al., clearly teach the device and method of manufacturing a devise as claimed in claims 1-4, 7-11, 13-23, 25-27 and 29-33.

Claims 1-8, 13-20, 22-24 and 30-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Frid (6,273,084).

Frid teaches an inhalation, drug delivery device (Figure 15) and method of making a drug delivery device, for delivering to a patient a drug composition from a container (3) which contains the drug composition, the container adapted to be placed in a dispensing mode thereof on application of an actuating condition thereto, wherein the device comprises: a dispensing unit (1) adapted to receive the container (3), the dispensing unit having an actuating mechanism (10,13, & 5) operable to apply the actuating condition to the container and an outlet (11) through which the drug composition is dispensable from the device (Figure 15); and a removable casing unit (2) for the dispensing unit (1); and wherein:- the dispensing (1) and casing units (2) have securing features (18, 21, & 25) for releasably, fixedly securing the units together; and the dispensing unit (1) is operable to apply the actuating condition to the container when fixedly secured to the casing unit (2) and when independent from the casing unit. Thus, Frid teaches a device meeting the limitations of claims 1 and 22. See: col.1, lines 38-61 and Figures 1, 2 & 15.

Frid teaches that the device can be moved into an open state (Figure 1) and a closed state (Figure 2) in which the casing unit (2) is able to enclose the dispensing unit (1) with the container received therein, and an open state which enables the actuating mechanism of the dispensing unit to be operated to apply the actuating condition to the

container and for the resultant dispensed drug composition to be discharged from the outlet, thus meeting the limitations of claims 2, 23 and 32-33. The device shown in Figures 1, 2, and 3 of Frid are hand held, hand actuated devices, thus meeting the limitations of claim 3, 5-6, and 24 . See: col. 1, line 62 – col. 2, line 5.

Frid shows the dispensing unit (1) as being held in place in the device (Figures 1, 2 &15) by the projecting studs (18) and recesses 19 and 21 which interact with the case (2) via opposed openings (25), thus meeting the limitations of claims 4. See: col. 3, lines 19-49 and Figures1, 2 & 15.

Frid teaches as that the user actuates the canister by pressing down on the canister while holding the device stationary. See: col. 1, lines 38-61; col. 4, lines 20-2; and Figure 15. Therefore, Frid teaches the actuation condition as claimed in claims 7, 8, and 30 and the valve and container as claimed in claims 15-17 and 31. See: col. 2, lines 18-25; col. 4, lines 17-25 and Figure 15.

In regard to claims 13-20, Frid teaches the dispensing unit (1) as having a spray nozzle (13) that is adapted to receive the valve stem (10) and is arranged to direct than aerosol spray through the outlet. See: col. 3, lines 8-12 and figure 8. Thus Frid teaches a nozzle arrangement as claimed in claim 15. See: col. 3, lines 1-12.

Thus, Frid clearly teaches the device and method of manufacturing a devise as claimed in claims 1-8, 13-20, 22-24 and 30-33.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 9-12, 21 and 25-29 are rejected under 35 U.S.C. 103(a) as being obvious over Frid (6,273,084), as discussed above, and further in view of Rand et al., (WO 98/56444).

Frid teaches an inhalation, drug delivery device (Figure 15) and method of making a drug delivery device, for delivering to a patient a drug composition from a container (3) which contains the drug composition, the container adapted to be placed in a dispensing mode thereof on application of an actuating condition thereto, wherein the device comprises: a dispensing unit (1) adapted to receive the container (3), the dispensing unit having an actuating mechanism (10,13, & 5) operable to apply the actuating condition to the container and an outlet (11) through which the drug composition is dispensable from the device (Figure 15); and a removable casing unit (2) for the dispensing unit (1); and wherein: the dispensing (1) and casing units (2) have securing features (18, 21, & 25) for releasably, fixedly securing the units together; and the dispensing unit (1) is operable to apply the actuating condition to the container when fixedly secured to the casing unit (2) and when independent from the casing unit. However, Frid lacks the counter mechanism claimed in claims 9-12 and 25-29 and the additional dispensing unit as claimed in claim 21.

Rand et al., teach an inhaler comprising an external housing (1) with a counter mechanism (13) wherein the first member comprises a pinion carried by a shaft through the lost motion coupling and the second member comprises a rack, thus

meeting the counter mechanism as claimed in claims 9-12 and 26-29. The Rand et al., reference teaches that the dispensing mechanism is useful in the treatment of respiratory disorders and that the counter allows the user to view the number of doses remaining in the container before the contents have been exhausted. Moreover, the Rand et al., reference teaches that metered dose inhalers are well known for delivering medicaments to the mouth and the nose for treatment of respiratory disorders. See: page 1, lines 1-34; page 4, lines1-9; page 5, lines 24-35; page 6, lines 26-33 and Figures 1 and 7.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the drug delivery device, as taught by Frid, by adding a counter mechanism as for showing the number of doses remaining in the drug delivery device, as taught by Rand et al., because of the reasonable expectation of obtaining a drug delivery device which provides a user with information about the remaining life of the product.

Conclusion

Wakefield et al., US 2002/0056449 A1 is being supplied as pertinent prior art, particularly relevant is Figure 7.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clinton Ostrup whose telephone number is (571) 272-5559. The examiner can normally be reached on M-F 7:30-5 pm with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Clinton Ostrup
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12/20/07